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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,818	01/09/2002	David R. Elmaleh	MGA-004.25	2433

25181 7590 10/21/2004

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EXAMINER

JONES, DAMERON L

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/530,818	Applicant(s) ELMALEH ET AL.	
	Examiner D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 7/22/04 wherein the claim status is as follows: claims 1, 9, and 12 amended; claims 2-7 and 13-18 canceled; and claims 8, 10, and 11 are as previously presented.

Note: Claims 1 and 8-12 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 7/22/04 to the rejection of claims 1 and 8-12 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 4/21/04 and those set forth below.

112 Second Paragraph Rejections

The rejection of claims 1 and 8-12 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 4/21/04 and those set forth below.

Applicant asserts that the claims are not vague and indefinite because of the various ways by which the radionuclide may be placed in spatial proximity with the targeting moiety. The various ways include a covalent or non-covalent chemical bond, incorporation of the targeting moiety and radionuclide into a confined (i.e., a liposome), attaching both the targeting moiety and radionuclide to a matrix, and attaching the radionuclide to the targeting moiety through a chelating structure. Applicant goes

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further to state that the cited modes by which the radionuclide may be placed in spatial proximity with the targeting moiety cited in the examples and the specification are not meant to be read as limitations into the claims, but rather are to illustrate that one of ordinary skill in the art would understand what is meant by 'associated with' and would know the metes and bound of the claims.

It is the Examiner's position that the claims are vague and indefinite. Not only are the claims not clear and concise, but also Applicant's position is that the definition of the phrase extends beyond that of the disclosure. Applicant is once again respectfully requested to clarify the claims in order that one may readily ascertain what is being claimed.

103 Rejections

The 103 rejection of claims 1 and 8-12 under 35 USC 103(a) as being unpatentable over Calenoff (US Patent No. 6,025,477) in view of Conti et al (US Patent No. 6,331,287) and in further view of Fritzberg et al (US Patent No. 5,175,343) is MAINTAINED for reasons of record in the office action mailed 4/21/04 and those below.

Applicant asserts that the primary reference, Calenoff, is directed to an antibody which specifically binds to an atherosclerotic plaque specific antigen. Thus, since the targeting moiety is an antibody and the instant invention does not read on antibodies, the instant invention is distinguished over the cited prior art. In addition, Applicant asserts that neither Conti et al nor Fritzberg et al make up for the deficiencies of the primary reference.

The instant invention is not limited to a specific group or groups of targeting moieties. Thus, if antibodies are excluded from the instant invention, the claims are not consistent with what is present in the specification. In particular, pages 2-3, bridging paragraph (see also pages 6-7, bridging paragraph), disclose that particularly preferred targeting moieties comprise components of the processes involved in plaque formation and growth as well as specific binding partners thereto. The disclosure goes further to specifically list (i) through (vi) as set forth in independent claim 1. In addition, it is noted that on page 5, lines 25-27, a targeting moiety has been defined as any molecule or biological entity that targets cardiovascular tissue or thrombi, or any molecule or biological entity that is easily converted to such a molecule or biological entity. Hence, if the specification discloses that antibodies and binding fragments thereof are preferred targeting moieties, it is unclear how antibodies that bind to plaques, as set forth in Calenoff, are excluded from the instant invention.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1616

October 18, 2004